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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,386	01/08/2002	Meir Shinitzky	SHINITZKY=4	5565

1444 7590 03/25/2003

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EXAMINER
SACKEY, EBENEZER O

ART UNIT	PAPER NUMBER
1626	8

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/937,386	SHINITZKY ET AL.
Examiner	**Art Unit**
EBENEZER SACKEY	1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 20, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above, claim(s) *1 (in part) 2-4, 6-8, 10, 23-24 and 27-43* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *13 and 14* is/are rejected.

7) ☒ Claim(s) *5, 9, 11-12, 13 (in part) 14-22, 25 and 26* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Preliminary amendment A, filed on 1/8/02 and Preliminary amendment B and Information Disclosure Statement filed on 2/20/02 respectively is acknowledged and has been entered into the file.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Applicants may need to provide a more legible Appendix A since some of the structures in the current one is not legible.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the

contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 (in part), wherein Y is CHOH, X is H, R is phenyl and claims 5, 9, 11-12, 13 (in part) 14-22, 25 and 26 are, drawn to compounds, compositions and methods of use.

Group II, claim(s) 1 (in part), wherein Y is CHOH, X is H, R is phenyl and claims 5, 9, 11-12, 13 (in part) 14-22, 25-26 and 27-30 are, drawn to compounds, compositions and methods of use.

Group III, claim(s) 1 (in part), wherein Y is CHOH, X is H, R is phenyl and claims 5, 9, 11-12, 13(in part) 14-22, 25-30 and 31-35 are, drawn to compounds, compositions and method of use.

Group IV, claim(s) 1 (in part), wherein Y is CHOH, X is H, R is phenyl and claims 5, 9, 11-12, 13(in part) 14-22, 25-35 and 36-37 are, drawn to compounds, compositions and methods of use.

Group V, claim(s) 1 (in part), wherein Y is CHOH, X is H, R is phenyl and claims 5, 9, 11-12, 13 (in part) 14-22, 25-37 and 38-43 are, drawn to compounds, compositions and methods of use.

Group VI, claim(s) 1, wherein Y is $(CH_2)_m$, or C=O, wherein m is 0-3, X is alkyl, CH_2OH, CH_2Oacyl, or CH_2acyl, R is H, cation, or alkyl and claims 1-4, 6-8 and 10-43.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2,

they lack the same or corresponding special technical features for the following reasons: the various claims of Groups I-VI herein lack unity of invention under PCT Rule 13.0 and 13.2 since the compounds and compositions defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The substituents on compounds of formula (I) and the composition containing same vary extensively and when taken as a whole result in vastly different compounds and composition. Each group of invention is classified in different classes with a plethora of subclasses. Illustrations of the different inventive concepts may be made by the reference to the Examples of the instant application. Accordingly, unity of invention is considered lacking and a restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter imposes a burden on any examination of the claimed subject matter. Moreover, the literature search for the methods of claims 25-26 would be different as for example, a reference for treating leukemia (claim 28) and would not be in the same reference book for the compounds

or compositions of Group I. During a telephone conversation with Sheridan Neimark on 12/30/02 a provisional election was made with traverse to prosecute the invention which includes species of claim 9, i.e., a pharmaceutical composition comprising phenyl 1,3-cyclic glycerophosphate. The Examiner has built a subgeneric group inclusive of applicants species. Such is disclosed in Group I. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2-4, 6-8, 10, 23-24 and 27-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The following generic concept as depicted in claim 1 is identified for examination along with the elected embodiment: Y is CH(OH); X is hydrogen; R is phenyl. The remaining subject matter of claims 1 (in part) 2-4, 6-8, 10, 23-24 and 27-43 in their entirety stands withdrawn from further consideration as constituting other patentably distinct inventions. The withdrawn subject matter in their entirety is properly restricted as said subject matter differs in structure and element from the elected subject matter so as to be patentably distinct therefrom, i.e., a reference which

anticipated the elected subject matter will not render obvious the withdrawn subject matter and additionally, the fields of search are not co-extensive.

Applicants should know that the intended use of the composition is given no patentable weight. Additionally, if applicants restrict the claims to such as defined in Group 1, the compounds and methods of use commensurate in scope therewith would be allowable.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for human breast cancer cells and T-leukemia cell lines, does not reasonably provide enablement for malignant diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a pharmaceutical composition for the treatment of malignant diseases and disorders and blood malignancy. It is noted that the specification provides disclosures for the effects of cyclic phosphates on differentiation of human breast cancer cells and T-leukemia cell lines see pages 29 and 30, which are drawn to those specific malignancies. Malignancies appears in various forms. It is not believable in view of the contemporary knowledge of the art that one or more related compounds would have the capacity to treat an extraordinary amount of malignancies which require different pathways and mechanisms. The claims as recited would give rise to undue experimentation to one of ordinary skill to ascertain if all known malignant diseases or disorders fall under these claims. One of ordinary skill in the art would not extrapolate the broad spectrum of applicability asserted in the instant claims from the limited examples and disclosure of the instant application.

For rejections under 35 U.S.C. 112, first paragraph, certain factors must be considered under the holding in *In re Wands,*8 U.S.P.Q. 2d 1400, 1404 (CAFC, 1988):1) the nature of the invention is that of using

compounds and compositions of formula (I) in treating malignant disorders or diseases; 2) various malignant diseases and disorders are known in the art; 3) the level of predictability is low, as is true of most biological and chemical systems; 4) the amount of guidance provided by the inventors is minimal since the disclosure is limited to exceedingly few examples i.e., breast cancer cell and T-leukemia cell lines; no teaching as to how the examples correlate to all malignant diseases and disorders. The instant specification provides little direction for treating malignant diseases and disorders commensurate in scope with the instant claims; 5) the existence of working examples is limited to the preparation of specific compounds and the differentiation of human breast cancer cells and T-leukemia cell lines as note pages 29 and 30 of the specification; 6) therefore, an undue quantity of experimentation would be needed to make the invention based on the content of the disclosure.

At best, the malignant diseases or disorders currently asserted for in the instant claims would be more adequately described as the disorders of claims 15 and 16. Although claims 13 and 14, are outside the criteria as

laid out in *In re Wands,* the malignant disorders of claims 15 and 16, would meet the criteria as laid out in *In re wands*. "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experiment should proceed." *In re Wands,* 8 U.S.P.Q. 2d 1400, 1404 (CAFC, 1988).

The disclosure is devoid of disclosures which would direct the skilled artisan to all malignant diseases and disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS

March 24, 2003

Sreeni Padmanabhan 3/24/03

Supervisory Patent Examiner

Art Unit 1617, Group 1600

Technology Center 1